II. Amendment to the Specification

The Office Action objects to the description of Fig. 2, stating that it would be more appropriate to use Figs. 2a and 2b instead of Fig. 2 to describe the drawings. Accordingly, the specification has been amended in accordance with the suggestions made by the Office Action, as detailed in the "Amendments to the Specification" section of this submission.

Thus, the objection to the specification should be withdrawn.

III. Rejection of claims 10-12 and 14-20 under 35 U.S.C. 112, first paragraph

The Office Action rejected claims 10-12 and 14-20 under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of treating fibromyalgia, the method comprising subcutaneous or intramuscular administering a botulinum toxin to a patient with fibromyalgia, the botulinum toxin being administered at a first location, which is anatomically distinct from and/or anatomically distant from a second location at which second location the patient has fibromyalgia pain, wherein the first location and the second location are within a same dermatome, does not reasonably provide enablement for a method of treating fibromyalgia, the method comprising subcutaneous or intramuscular administering a botulinum toxin to a patient with fibromyalgia, the botulinum toxin being administered at a first location, which is anatomically distinct from and/or anatomically distant from a second location at which second location the patient has fibromyalgia pain, where the first location is not identified. Applicant respectfully traverses the rejection.

Applicants respectfully assert that scope of claims 10-12 and 14-20 are fully enabled by the specification, that is, one of ordinary skill in the art would be able to practice the claimed methods for treating fibromyalgia, without undue experimentation. As disclosed in the specification and stated by the Office Action, particular aspects of the specification are directed to methods of treatment of fibromyalgia pain, where botulinum toxin is administered at a first location that is anatomically distinct from and/or anatomically distant from a second location, the second location having the fibromyalgia pain.

As one of ordinary skill in the art understands, and as described in the instant specification, there is no one specific location at which a patient suffering from fibromyalgia can experience fibromyalgia pain (see Examples 1-10 on pages 23-30 of the specification), fibromyalgia pain can present itself at different locations in different patients. However, in light of the disclosure of the instant

specification, the practitioner is clearly directed as to where to administer a botulinum toxin (first location) relative to the *location* of a fibromyalgia pain (second location) in a particular patient being treated, as the first location is relative to the second location, that is, to where the fibromyalgia pain presents itself.

Taking the instant disclosure as a whole, one of ordinary skill in the art is provided with specific criteria to determine where to administer a botulinum toxin (first location) relative to and for treating fibromyalgia pain (second location). Firstly and in one aspect of the disclosure, the first location can be "anatomically distinct from and/or anatomically distant from a second location."(page 12, lines 19-20 of the specification). As clearly defined in the specification on page 12, lines 21-23, anatomically distinct means "…that the functional anatomy of the first and second locations is not contiguous, in a functional anatomical sense", clearly a definition understood by one of ordinary skill in the art familiar with basic human anatomy. For example and as one aspect of the invention, one of ordinary skill in the art would understand that the first location (botulinum administration) and second location (fibromyalgia pain) are not *both* located at the same leg, or the same arm, or both on the head, for example (page 12, lines 23-25). Additionally, many examples of distances between the location of botulinum administration (first location) and fibromyalgia pain (second location) are provided in the specification, at least at page 20, lines 6-21, for example.

Additionally, the instant specification provides an example (Example 10, pages 29-30) where fibromyalgia pains located at a particular location (second location) are alleviated due to botulinum toxin administration at an anatomically distinct and distant location (first location). In this example, fibromyalgia pains in the lower back (second location) are alleviated by administration of botulinum toxin into the shoulders (first location), an anatomically distinct and distant location, that is, a location that is not contiguous, in a functional anatomical sense, with the area of fibromyalgia pain, in this example, the lower back (page

30, lines 6-10). Additionally, the site of administration (shoulders) and pain location (lower back) are not within the same dermatome (see Figure 3 of the specification). In other examples, the location of administration of botulinum toxin and the location of pain can be within the same dermatome (page 11, line 10-13) however, the specification discloses that the neurotoxin can be administered to a dermatome that is adjacent to the dermatome which contains the site of pain origin (page 20, lines 1-3 of the specification).

The inventor has provided a clear disclosure to enable the practice of methods for treating fibromyalgia pain located at a location (second location) that is anatomically distinct and distant from the location at which a botulinum toxin is administered (first location). Respectfully, there is no requirement that the instant specification provide specific, exact examples of all the combinations of first locations (botulinum administration), second locations (fibromyalgia pain), and distances therebetween, that can be treated in accordance with the teachings of the present disclosure and scope of the claims. Applicants are assuming that the Office Action is citing this requirement in light of the comments on page 5 of the Office Action where it is stated that "…the breadth of the claims is broad and encompasses unspecified variants regarding the site of administration (a first location), which is not adequately described or demonstrated in the specification".

Respectfully, the absence of particular variants/examples does not render the instant written description inadequate to support claimed methods for treating fibromyalgia at a second location that is anatomically distinct and/or distant from a site where a botulinum toxin is administered (first location). As stated by the Federal Circuit, "A claim will not be invalidated on section 112 grounds simply because the embodiments of the specification do not contain examples explicitly covering the full scope of the claim language. *That is because the patent specification is written for a person of skill in the art, and such a person comes to the patent with the knowledge of what has come before*. Placed in that context, it

is *unnecessary to spell out every detail* of the invention in the specification;" emphasis ours, (*Falker-Gunter Falkner v. Inglis* (Fed. Cir. 2006, 05–1324) 79 USPQ2d 1001, 1007 (copy attached).

Thus, a person of ordinary skill in the art, clearly familiar with basic human anatomy, would clearly comprehend the meaning of the claim limitations of first and second locations being at anatomical locations that are distinct and/or distant from one another. Additionally, in light of well-known human anatomy, fibromyalgia and the definitions and examples provided in the instant specification, a person of ordinary skill in the art would clearly be convinced that the inventor possessed the claimed invention and that the specification enables the practice of the claimed invention, without undue experimentation.

Thus, the rejection should be withdrawn.

III. Rejection of claims 10-12 and 14-20 under 35 U.S.C. 112, second paragraph

The Office Action rejected claims 10-12 and 14-20 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which the applicant regards as the invention. Applicant traverses this rejection.

The Office Action states that claims 10-12 and 14-20 are indefinite as to where the first location for administering a botulinum toxin is, since the claim recited that the first location is anatomically distinct from and/or anatomically distant from the second location (pain location).

As discussed above, the specification, taken as a whole and read by one of ordinary skill in the art, clearly directs a practitioner of the claimed methods to where the first location can be. As disclosed in the instant application, the first location is (a) located relative to the second location at which a fibromyalgia pain present itself, and (b) must be at a location that is "anatomically distinct from and/or anatomically distant from a second location.", which is the location of the pain (page 12, lines 19-20 of the specification). As defined in the specification on page 12, lines 21-23, anatomically distinct means "…that the functional anatomy of the first and second locations is not contiguous, in a functional anatomical sense", clearly a definition understood by one of ordinary skill in the art familiar with basic human anatomy, as discussed above.

Thus the rejection should be withdrawn.

III. Conclusion

All issues raised in the Office Action have been addressed. Reconsideration and allowance of claims 10-12 and 14-20 is requested.

The Commissioner is hereby authorized to charge any fee(s) required or necessary for the filing, processing or entering of this paper or any of the enclosed papers and to refund any overpayment to deposit account 01-0885.

Respectfully submitted,

/Claude L. Nassif/

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Attachments: *Falker-Gunter Falkner v. Inglis* (Fed. Cir. 2006), 05–1324

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